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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/687,327	Applicant(s) BOGA ET AL.	
	Examiner Ginny Portner	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☒ Claim(s) 9-14 is/are objected to.
- 8) ☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>all 4 ids</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-26 are pending; there are two claims labeled claim 25, the second should be numbered claim 26 (37 CFR 1.126).

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-24 in the reply filed on December 19, 2005 is acknowledged.
2. Claims 25-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 19, 2005.

Information Disclosure Statement

1. The information disclosure statement filed July 14, 2004; November 18, 2004; May 27, 2005 and December 12, 2005 have been considered.

Claim Objections

2. Claim 9 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 9 does not modify the composition/device of claim 1 from which it depends, but only modifies the recited intended use of the device of claim 1; claim 9 is therefore not further limiting of the claimed invention of claim 1.

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Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 5-8, 10, 14, 16, and 19 of this application conflict with claims 23, 27-28, 3, 36, 38 and 42 of Application No. 10/687,270. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation

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between the applications. See MPEP § 822. The recited intended use not defining a structural distinction between the claimed inventions.

6. Claims 1, 5-8, of this application conflict with claims 1, 10 (ammonia), 11-13 of Application No. 10/687,269. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822. The recited intended use not defining a structural distinction between the claimed inventions.

7. Claims 1, 5, 7-8, 10 and 14 of this application conflict with claims 1, 3, 5-6 of Application No. 10/961,676. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822. The recited intended use not defining a structural distinction between the claimed inventions.

Claim Objections

8. Claim 9 is objected to because of the following informalities: Claim 9 recites the phrase “*helicobacter pylori*”; the term “*helicobacter*” should be capitalized as it is a proper name of a bacterial species.

9. Claim 10 should recite ---- further comprises a substrate, wherein the indicating agent is applied to the substrate--- as it adds an additional structural component not claimed in claim 1.

10. Claim 14 recites the term “polypropylene/polyethylene film”; is this term intended to be the combination of both polymers does the “/” mean “and/or”; clarification of what is intended by the character “/” is requested. Appropriate correction is required.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 15-16 recite the limitation "carrier portion of the device" in reference to the device of claims 10 and 1, but neither device of claims 10 and 1 comprise a carrier portion. The device of claim 1 comprises an indicating agent and the device of claim 10 defines the device to be the indicating agent applied to a substrate. Neither the agent nor the substrate have been structurally defined to comprise a carrier portion nor a passage located in a carrier portion. There is insufficient antecedent basis for this limitation in claims 1 and 10 from which claim 15 depends.

Please Note: The examiner is reading the invention of claim 1 to be directed to a visual indicating agent that is color sensitive to ammonia as that is what the claimed device comprises. No additional structural components are claimed, therefore the invention is the visual indicating agent, the agent being the device that is color sensitive to ammonia. Various embodiments are claimed, such as claim 17 which is the agent in solution that serves the recited intended use as a device for detecting ammonia odors.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

14. Claims 1, 9-23 are rejected under 35 U.S.C. 102(b) as being anticipated by D'Angelo et al (US Pat. 5,989,840).

D'Angelo et al disclose the instantly claimed invention directed to a device that comprises :

Instant claim 1: a visual indicating agent (see D'Angelo et al , col. 5, lines 65-67 and col. 6, lines 1-36) that is color sensitive to ammonia (see D'Angelo et al col. 2, lines 62 "abnormal levels of ammonia and detection of an antibody to the H. pylori"; see col. 8, Example 12).

Instant claim 9: wherein the detection of ammonia is correlated with Helicobacter pylori urease (see D'Angelo et al, abstract; col. 2, lines 46-52 and col. 1, lines 65-66) infection.

Instant claims 10-11: the indicating agent is applied, coated on a substrate ("Impregnated with the necessary reagents for analysis", (see D'Angelo et al col. 3, lines 40, which is a type of applying or coating the substrate, the substrate being a chemical sensor strip, see col. 3, lines 38-54;).

Instant claim 14: the substrate is defined to be filter paper (see D'Angelo et al col. 5, lines 56-57) which is further defined to be cellulose to include cellulose (see D'Angelo et al col. 6, line 32 "filter paper", and line 63).

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Instant claim 15, 21: wherein the substrate is located in a passage of a carrier portion (“A chemical sensor strip can be incorporated as an integral part of the device (D’Angelo et al col. 3, lines 38-40)”; also see Figure 3b, that shows passage of a carrier portion that comprises the substrate upon which the indicating agent is applied (see D’Angelo et al col. 6, lines 43-55 “sensor layer”): “

Instant claim 16, 22: the substrate covers one end of a carrier portion of the device (see D’Angelo et al , col. 7, lines 28-31; Figures 5A and 5B: “A chemical sensor strip 21 can be fixed onto the cap through a solid backing layer 22 with a hole aligned with 20. The cap defining a cylindrical structure of the bottle and device shown in the figures).

Instant claim 17: the indicating agent is in solution (see D’Angelo et al col. 5, line 57 “reagent solutions”

Instant claim 18: the visual indicating agent is in powder form (“prepared by drying porous hydrophilic material such as filter paper soaked with reagent solutions”, see D’Angelo et al col. 5, lines 55-56).

Instant claims 13, 19-20, 23: The device of D’Angelo et al comprised a plurality of zones, the zones presenting reference colors for semiquantative determination of ammonia levels produced by *Helicobacter pylori* infection (see Figure 4A and 4B (the test strip being substantially flat); (col. 8, lines 59-67) four different reference ammonia levels were placed/printed on the test strip for evaluation. Each reference ammonia level produced a specific chromogenic reference color and were used to evaluate two samples applied to the test strip (conducted “simultaneously”). Each reference concentration of ammonia produced a distinct difference in color, the reference

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color being produced from ammonia being applied/printed on the test strip zones (also see D'Angelo et al col. 5, lines 37-39 and 43).

D'Angelo et al anticipates the instantly claimed invention as now claimed. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

15. Claims 1-5, 9-11, 14-16, 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Duan et al (US Pat. 6,406,669).

Duan et al disclose the instantly claimed invention directed to a device that detects ammonia that comprises :

Instant claim 1, 9: a visual indicating agent (see Duan et al, title, abstract (polyaniline film), col. 5, lines 29-34 “a color change from green to blue was observed” the recited intended use of the device not defining over the applied prior art.

Instant claims 2-4: detection range including 20-500, 50-400, 75-300 ppm (see abstract, “detection limit of 1 ppm (v/v) for ammonia, with a linear dynamic range from 180 ppm to 18,000 ppm.”

Instant claim 5: the visual indicating agent having the general formula shown (see Figure 2, disclosed species “polyaniline, abstract”).

Instant claims 10-11: the indicating agent is applied, coated on a substrate (Duan et al, abstract “deposited on a polyethylene surface”, a type of being applied and coated on a substrate surface, see abstract, “transparent polyaniline film”(see col. 3, lines 39-41; col. 4, lines 52-53 “inside a transparent tube”).

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Instant claim 14: the substrate is defined to be a polymer film (a type of non-woven fabric) of aniline (see Duan et al col. 4, lines 38-41 “uniform polyaniline film was deposited” on the inner wall of the polyethylene tube).

Instant claim 15, 21: wherein the substrate is located in a passage of a carrier portion (Duan et al , col. 4, lines 49-56 “located inside a transparent tube”)

Instant claim 16, 22: the substrate covers one end of a carrier portion of the device (see Duan et al , col. 4, lines 54-56 “This can be achieved by evacuating tube 16 downstream from polyaniline film 14, or by pressurizing tube 16 upstream from polyaniline film 14.” (see Figure 1)).

Duan et al anticipates the instantly claimed invention as now claimed. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

16. Claims 1, 5-6 , 10 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (US Pat. 3,842,103 issue date 1974).

Smith et al disclose the instantly claimed invention directed to a:

Instant claims 1, 5 and 6: Visual indicating agent that is color sensitive to ammonia (see col. 1, lines 25-28 “2-[4,4’-bis(dimethylamino)-benzohydryl).

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Instant claim 10: The indicating agent is disclosed to be a paper coating composition (see col. 1, 21-22).

Instant claim 17: The indicating agent was produced as a solution (see col. 2, lines 16 “solution”) and was shown to be reactive with ammonia (see col. 2, line 19).

Smith anticipates the instantly claimed invention because the recited intended use of the claimed invention does not define over the applied prior art.

17. Claims 1, 5, 7, 9, 12 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Rottman et al in light of evidence provided by Hart et al that acid fuchsin dye is pararosaniline.

Rottman et al disclose the instantly claimed invention directed to a:

Instant claims 1, 5, 7: Visual indicating (see page 5732, col. 2, paragraph 1, figure 2, frame C) agent (see abstract) that is color sensitive to ammonia, wherein the indicating agent is pararosaniline (also known as acid fuchsin in light of evidence provided by Hart et al, abstract and Figure 4, page 5734; figure 1, page 5731) .

Instant claim 12: the visual indicating agent was entrapped in a pseudomicelle type particle (see page 5733, col. 2, bottom of paragraph 1), referred to as a SiO₂ sol-gel (abstract), which results in nanosize particles.

Instant claim 17: The indicating agent was produced as a solution (see page 5731, col. 1, paragraph 4 “Entrapment Procedure”).

Rottman et al inherently anticipates the instantly claimed invention because the recited intended use of the claimed invention does not define over the applied prior art.

1. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or

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unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

2. Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. v IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that the same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art."

18. Claims 1, 10, 11, 12, rejected under 35 U.S.C. 102(e) as being anticipated by Melker et al (effective filing date May 23, 2001), *Pub. No. 2005/0037374 A1*.

Instant claims 1, 10-11: Melker et al disclose the instantly claimed invention directed to an ammonia testing device, the device comprising a visual indicating agent that is color sensitive to ammonia (see Melker et al, [0010, 0044, 0122 "compounds that change the color of bodily fluids for detection by the naked eye or compounds that are readily identified in bodily fluids using sensor technology", and claims 8 and 34 "ammonia"]).

Instant claim 12: The indicator being applied to the surface of nanoparticles (see page 16, claims 11- 16 and 18). Melker et al anticipates the instantly claimed invention as now claimed.

19. Claims 1, 5, 8, 9, 10, 14 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al (EP 1160569 A2).

Wu et al disclose the instantly claimed invention directed to a:

Instant claims 1, 5, 8, 9: Visual indicating agent [0063, page 8, line 57]) that changes color, the agent being alpha-naphtholbenzein (see Wu et al, page 19, claim 20), wherein the agent is

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incorporated into an analytical device (see page 20, claim 28) for analysis of a gaseous sample (see page 20, claim 26; [0020]).

Instant claims 10, 14, 18, wherein the agent is applied to a substrate (see page 4, [0017 “incorporating an indicator reagent”], which is referred to as a carrier matrix, another term for substrate, the substrate defined to include cellulose (see page 11, [0084-0085; 0092]) is dry (see [0029 “dry phase test strip”, and therefore would comprise a powder form [0095])).

While Wu et al do not discuss ammonia as an analyte, the device and visual indicating agent are the same or equivalent device and agent instantly claimed. Wu et al inherently anticipates the instantly claimed invention because the recited intended use of the claimed invention does not define over the applied prior art.

3. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594
4. Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. V IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states “Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that the same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.”

20. Claims 1, 9, 10-11, 14 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Dobler et al (EP 1037045 A2) .

Dobler et al disclose the instantly claimed invention directed to a device that detects ammonia in breath (a gaseous sample, see Dobler et al abstract):

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Instant claims 1, 9, 10-11: Visual indicating agent (“membrane is coated with a pH chromogenic mixture which changes color if ammonia gas passes through”, abstract; also see page 4, [0027-0032 and Table 1])) that changes color; the recited intended use does not define over the applied prior art.

Instant claims 10, 14, 18, wherein the agent is applied to a substrate (abstract, membrane; see page 4, [0026, page 4”nylon”, “polypropylene”]) which is in turn adhered to a polystyrene material used for a handle (see page 4, [0031]), polystyrene being a type of non-woven material. The device is formulated into a “Powder test kit” more improved shelf life and stability of reagents (see page 2,[0006]).

Dobler et al anticipates the instantly claimed invention as now claimed.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

5. Inherently the reference anticipates the now claimed invention. *Atlas Powder Co. v IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states “Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. The Court further held that this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art.”

21. Claims 1, 9-11, 14-20 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Baldwin et al (WO97/30351).

Baldwin et al disclose the instantly claimed invention directed to a device that comprises

Instant claim 1: a visual indicating agent that is color sensitive to ammonia (see Baldwin abstract

“indicator system which exhibits a detectable visible change in the presence of ammonia”; also see page 5, paragraphs 1-2, page 6, paragraphs 1-3; page 7, whole page).

Instant claim 9: wherein the detection of ammonia is correlated with *Helicobacter pylori* urease

(see Baldwin et al, page 14, paragraph 1, line 2 “urease”) infection (see Baldwin et al, abstract “Ammonia in the exhaled breath of human subjects, for example subjects infected with *H.pylori*”); also see Baldwin page 15, paragraph 2 “capable of distinguishing subjects who are infected with *H.pylori* from those who are not”).

Instant claims 10-11: the indicating agent is applied to a substrate (see page 3, paragraph 1, lines 1-14 “the indicator will be absorbed (applied) or coated onto a preformed support which may be the interior surface of the tube into which the breath to be tested is exhaled”).

Instant claim 14: the substrate is cellulose, non-woven fabric (nylon) (see Baldwin et al, page 3, paragraph 1, especially line 4).

Instant claim 15, 20, 22: wherein the substrate is located in a passage of a carrier portion of the device: “The indicator system (indicator coated or absorbed to a substrate, such as beads or other particulate material, see Baldwin, page 3, paragraph 1) may be incorporated into the porous support (the porous support defines a carrier portion of the device, as it carries the sample as well as the substrate that comprises the indicator system) so that it is present uniformly throughout the support” (also see Baldwin, page 9, lines 1-4 and whole paragraph; also see Figures 3-5, Figure 5 being a tube (see figure 3, cylindrical structure) that comprises a passage that is open at least one end (Figure 3, see number 21, a carrier portion; number 22, carrier for indicator system sensitive to ammonia; open at left and right end).

Instant claim 16: the substrate covers one end of a carrier portion of the device (see Baldwin page 10, paragraph 3, “attached to the end of the tube 11”; also see Baldwin Figure 5, and page 12, paragraph 2, porous filling 32; also

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see page 1, paragraph 2, and Figures 3-4, "porous mass 22 in which is located an acidic medium to absorb the ammonia and at least part of the indicator system". The substrate (porous material) is at one end of the carrier portion of the device, and comprise the indicator agent system.)

Instant claim 17: see Baldwin figure 3, and page 11, paragraph 1-2, the indicator system is in a solution that covers one end of the passage (see Figure 3, number 25, which is a container that comprises a solution of the remaining parts of the indicator system. The container 25 has an opening in one wall thereof into which the end of the tube 21 is inserted) that comprise the substrate carrier portion of the device.

Instant claim 18: the visual indicating agent is in powder form (powder form is being read to include dry reagents: please see Baldwin page 10, paragraphs 4-5 and page 11, paragraph 1 "activated immediately prior to use by the addition of water"; "dry acid" ; "dry state would have a satisfactory shelf life prior to use").

Instant claims 19-20: reference color chart for the color to which the indicating agent will change when exposed to ammonia odors (see Baldwin page 4, paragraph 1, lines 14-18 "provided with a shade chart against which to compare the test result" when determining the presence of "larger amounts of ammonia". While the reference color chart is not shown in the figures, the colors would be printed on the shade chart described by Baldwin et al, the shade chart being a reference zone for the color to which the indicator agent changes.

Baldwin et al anticipates the instantly claimed invention as now claimed. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin et al (WO97/30351) in view of Boguslaski et al (US Pat. 5,420,016).

See discussion of Baldwin et al above. Baldwin et al disclose a breath testing device for the presence of ammonia odor that comprises both a breath collecting device and a visual indicating agent for aiding in the diagnosis of *Helicobacter pylori* infection, the device comprising a visual indicating agent that is color sensitive to ammonia (see abstract. Baldwin et al differs from the instantly claimed invention by failing to teach the test device formulated into kit form.

Boguslaski et al teach the formulation of an ammonia test device (see title, abstract) into kit form (see claims 9-15) in an analogous art for the purpose of aiding in the diagnosis of *Helicobacter pylori* infection.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to formulate the ammonia breath testing device of Baldwin et al into a kit form as taught by Boguslaski et al because Baldwin teaches and shows a test device to be non-invasive, speedy, accurate and can be used by personnel with only a small amount of training or a patient themselves (see page 2, paragraph 2) and Boguslaski et al provides guidance, teaches

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and shows the formulation of an ammonia detection device into kit form because “assembling the various system components into a test kit which makes its use more convenient and facile for the test operator (see Boguslaski et al, col. 7, lines 8-11).

In the absence of a showing of unexpected results Baldwin et al in view of Boguslaski et al obviate the instantly claimed invention because Baldwin et al clearly contemplated a test device that is non-invasive, speedy, accurate and can be used by personnel with only a small amount of training or a patient themselves and Boguslaski et al provides additional guidance and motivation for formulate the test into kit form for the realized advantage of a test that is “more convenient and facile for the test operator (Boguslaski et al, col. 7, line s 8-11)”. Baldwin et al in view of Boguslaski et al obviate the instantly claimed invention.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

25. Martino et al (US Pat. 5,814,370) is cited to show SiO₂ sol-gel produce nanoparticle size micelles (see col. 2, lines 40 “nanoclusters).

26. WO00/20852 is cited to show a sensor that comprises nanoparticles, color indicators that are responsive to ammonia (page 98, paragraph 1; page 90, paragraph 2 “emeraldine” ; page 91, paragraphs 1-2; page 30), ink jet application of reagents (see page 47, paragraph 2), detection of amines , analysis of breath (page 16; page 9 “gas sensors”; pg 54, last paragraph; straw or tube to collect sample of breath (see page 72, paragraph 1); page 96, paragraph 1)

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27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
March 15, 2006


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